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10/815,481	03/31/2004	Rajesh A. Patel	304142000900	8558

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1618	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,481	PATEL ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-87* is/are pending in the application.

4a) Of the above claim(s) *6,11-14,21,24-48 and 80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-10,15-20,22,23,49-79,81-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5-13-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response filed 5/13/2008 has been received. Claims 1-7 and 9-87 are pending in this action. Claims 6, 11-14, 21, and 24-48, and 80 are withdrawn.

Election/Restrictions

Applicants have requested that claim 28 be rejoined, because Applicants now aver that this claim was not subject to an election or restriction requirement. This claim was withdrawn because Applicants indicated that it does not read on elected species 2. See response filed 10/3/2007 at 12 (listing claims 1-11, 13, 15-24, 26 and 49-61 as reading on the elected species 2). If Applicants statement regarding which claims read on the elected species was in error, then Applicants should clearly indicate the error and provide an accurate listing of which claims read on the elected species, as required. For clarity of record, claim 28 is still withdrawn in reliance on Applicants earlier statements; claim 80, being quite similar to claim 28, is also withdrawn in reliance on the same previous statements by Applicant. If Applicants' still believe that these claims do in fact read on elected species 2, then Applicants' should clearly state that the listing of claims reading on species 2 in the paper filed 10/3/2007 was in error, and should clearly state which of the currently pending claims read on each of the elected species. Upon receipt of such a submission, the status of these claims will be reconsidered.

Double Patenting

Applicant is advised that should claims 1-5, 7, 9, and 62-63 be found allowable, claims 16-20, 22, and 65-67 will be objected to under 37 CFR 1.75 as being a substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7, 9, 10, 15-20, 22, 49-71, 83, 86 are 87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

The instant claims recite the limitation "wherein the device is uncoated" which is new matter. The specification does not discuss that the device may be uncoated. Recognizing that a positive recitation in the specification gives support for a commensurate negative recitation in the claims, it is noted that the specification at paragraphs [0021] and [0022] (in the published Application) discuss that the implant may have a hydrophobic coating. However, the instant

claims, which would forbid all coatings, not just hydrophobic coatings, are not supported by this recitation. It is also noted that the examples describe uncoated devices, but the devices described in the examples are AopH/EVA implants only, and do not provide support for the instant claims which are not limited to AopH/EVA implants (indeed, the elected species of drug is not AopH).

Claim Rejections - 35 USC § 102

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, and 86 are rejected under 35 U.S.C. 102(a) as being anticipated by Bibbiani et al. "Continuous Apomorphine Administration with Novel EVA Implants reduces the Risk of Motor Complications Compared to Pulstile Apomorphine in L-COPA-Naïve, MPTP-Lesioned Primates", of record (hereafter, "Bibiani").

Bibbiani teaches an uncoated EVA implant containing apomorphine, a drug of instant claims. The implant releases the drug in amounts consistent with those recited in instant claims, as it must because products of identical chemical composition cannot have mutually exclusive properties. The "Results" section of the reference also appears to indicate that the drug release levels are commensurate with those of the claims, and that release continues for 24 weeks (just less than six months). With regard to the recitation of delivery "through pores that open to the surface of said matrix" It is suggested that this implant is useful for treatment of Parkinson's disease. As discussed in the previous office action mailed 11/29/2007 (page 4) antioxidants are inherent because commercial EVA polymers include a small amount of BHT as an antioxident.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 71, 75, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bibbiani.

The teachings of Bibbiani are discussed above.

What is lacking from Bibbiani is:

1) teaching of the size of the implant

2) teaching of the drug loading (% drug)

3) teaching of including instructions for use with the implant (a "kit")

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to make the implant the appropriate size, to use the appropriate amount of drug, and to include instructions with the implant.

The size of an implant would depend on its future intended use, such as the site and subject for which the implant is intended (an implant intended for a mouse would be smaller than one intended for an elephant). The artisan would understand this, and would size the implant as appropriate for the subject and location for which the implant is intended.

The amount of drug in an implant is a matter of dosing, which the artisan understands effects the release kinetics of the drug from the matrix. Alteration of the amount of drug amounts to optimization of dosing, which is routine for a person of skill in the pharmaceutical arts.

With regard to the instructions for use, a person of ordinary skill would find it obvious to sell the implant along with instructions indicating to the end user how the implant should be used. The artisan would recognize that these instructions would make the product more easily used by the end-user, and increase the chances of success in treatment by ensuring that the end user had this knowledge.

Claims 11, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 71, 75, and 78 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bibbiani in view of WO 98/20864 (the 864 reference).

The teachings of Bibbiani are discussed above.

What is lacking is the teaching of an anti-inflammatory.

The 864 reference teaches the use of NSAID agents for treatment of Parkinson's disease.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include the NSAIDs of 864 in a kit in with the implants of Bibbiani. Combining multiple treating agents for treatment of the same disease or disorder is generally obvious. It would also be obvious to include the 864 NSAIDs in implants similar to those of Bibbiani, as such implants

are recognized as useful to delivery anti-Parkinson's medication. In order to avoid possible incompatibilities between the drugs, the artisan would use separate devices for the dopamine agonist and the NSAID.

Claims 11, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 71, 75, and 78 and 3, 4,18, 19, 54, and 53 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bibbiani in view of Patel “Buprenorphine Implants: Novel Treatment For Opiate Dependance.”

The teachings of Bibbiani were discussed above.

Bibbiani does not teach 33% vinyl acetate or the drug loading.

Patel teaches that EVA with 33% vinyl acetate are suitable for sustained release. Patel also teaches that a 75% drug loading is suitable.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to make the EVA implant of Bibiani with 33% vinyl acetate because Patel teaches that this is a suitable vinyl acetate concentration for an EVA sustained release implant. It would further be obvious to use a 75% drug loading, as Patel teaches this to be suitable.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 70, 71, 75, 78 and 64, 70 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bibbiani in view of US 3,689,634 to Kliment.

The teachings of Bibbiani were discussed above.

What is lacking is a teaching of washing

Kliment teaches washing polymer based implants with ethanol in order to remove impurities such as polymerization initiators (Example 3).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to wash the implant of Bibbiani with ethanol, as suggested by Kliment. The motivation is to remove impurities, such as polymerization initiators.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 70, 71, 75, 78 and 64, 70 and 81are rejected under 35 U.S.C. 103(a) as being unpatentable over Bibbiani in view of US 5,618,553 to Kelleher

The teachings of Bibbiani were discussed above.

What is lacking is a teaching of washing.

Kelleher teaches controlled release implants. Kelleher teaches that when no initial drug burst is desired, the implants should be washed in a solvent to remove the drug from the surface of the implant (col. 8, lines 12-36).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to wash the implant of Bibbiani with ethanol, as suggested by Kelleher. The motivation is to eliminate an initial burst, which the artisan understands may be undesirable depending on the intended use of the implant.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 71, 75, and 78 and 59-

61, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bibbiani in view of US 5,604,198 to Poduslo et al.

The teachings of Bibbiani have been discussed previously.

What is lacking in Bibiani is a teaching of lisuride.

Poduslo teaches that, like aopmorphine, lisuride is a known treating agent for Parkinson's disease.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to either add lisuride to the implants of Bibiani or to substitute lisuride for apomorphine therein. Obviousness stems from the notion that it is obvious to either combine two materials that are known to be used for the same purpose in order to effectuate that known purpose, or to substitute one material for the other when the two materials are known to serve the same function. Here, lisuride and apomorphine were both known to treat Parkinson's disease, and so it would have been obvious to substitute one for the other, or to combine the two.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 71, 75, and 78 and 59-61, 77, 81 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bibbiani in view of US 5,604,198 to Poduslo et al., Patel, and US 5,618,553 to Kelleher.

Bibbiani was discussed above.

What is lacking is:

1) 33% vinyl acetate in the EVA,

2) a washed implant, and

3) lisuride.

It was discussed above how Poduslo renders the use of lisuride obvious, how Patel renders the use of 33% vinyl acetate obvious, and how Kelleher renders washing obvious.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use lisuride, 33% vinyl acetate, and wash the implant. Each of these individual modifications is obvious for reasons discussed above, and it therefore follows that they are obvious in combination, because all of the required alterations to Bibbiani would be predictable either together or independent of one another. The conclusion that the alterations would be predictable is based on the fact that each of them are already independently known in the art.

Claims 72 – 79, 82, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabel in view of US 5,128,145 to Edgren.

The Sabel reference teaches and EVA matrix containing 70% L-Dopa (a dopamine agonist, also called levodopa). (p 715, Methods section). The matrix is 15mm x 30mm x 2mm in size (p 715, methods section), commensurate with the requirements of the claims. The matrix contains pores through which the L-Dopa dissolves into an aqueous environment (p 715, Results section). The release of the L-Dopa is commensurate with that required by instant claims. Figure 2 (A) and (B) show sustained release over more than 3 months, release of more than 1 mg per day, and release of more than 0.01 ng /ml plasma.

With regard to claims which require about 33% vinyl acetate in the EVA copolymer, the reference is silent on the amount of vinyl acetate, but notes that the procedure used is the same as that in a previous reference, namely the Freese reference, of record. The Freese reference teaches that the EVA copolymer was purchased from DuPont as ELVAX® 40P. According to the ELVAX disclosure, also of record, it does not appear that the 40P line is still available, however, the other ELVAX 40 products (40L-03 and 40W) have 40% vinyl acetate. It is understood that the Sabel reference also used EVA with about 40% vinyl acetate, which reads on instantly claimed about 33% vinyl acetate.

What is lacking is a teaching of a dopamine agonist that binds to one or more dopamine receptor subgroups, namely the elected species of lisuride.

Edgren teaches that lisuride and levodopa are both anti-Parkinson's drugs. Example 3.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to either add lisuride to the implants of Sabel or to substitute lisuride for levdopa therein. Obviousness stems from the notion that it is obvious to either combine two materials that are known to be used for the same purpose in order to effectuate that known purpose, or to substitute one material for the other when the two materials are known to serve the same function. Here, lisuride and levdopa were both known to treat Parkinson's disease, and so it would have been obvious to substitute one for the other, or to combine the two.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 71, 75, and 78 and 59-61, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of US 5,604,198 to Poduslo et al.

The Patel reference was discussed in part above. The Patel reference also teaches use of the drug buprenorphone, and that a sustained release over 6 months with release kinetics commensurate with instant claims is achieved upon implantation of the implant in a subject.

What is lacking is a teaching of lisuride.

Poduslo teaches that lisuride is a known treatment for Parkinson's disease.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to substitute lisuride for the drug of Patel. The motivation comes from Poduslo's teaching that lisuride is useful for treating Parkinson's disease. Thus, the artisan using the implant of Patel, but wishing to treat Parkinson's disease, would use lisuride instead of the drug of Patel. The artisan would expect success, because the EVA implant is non-erodable, and thus the artisan would only need to determine the appropriate dosing of lisuride (as compared to the dosing of Patel's drug), which is a matter of mere routine optimization.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 71, 75, and 78 and

59-61, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of Bibbiani US 5,604,198 to Poduslo et al.

The teachings of Patel were discussed above.

What is lacking is the use of lisuride.

Bibbiani was discussed above. Bibbiani teaches the use of anti-Parkinson's agents in an EVA implant that is very similar to Patel's implant.

Poduslo teaches that lisuride is an anti-Parkinson's medication.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use lisuride instead of the drug of Patel in Patel's implant. The motivation comes from Poduslo's teaching that lisuride is useful for treating Parkinson's disease. Thus, the artisan using the implant of Patel, but wishing to treat Parkinson's disease, would use lisuride instead of the drug of Patel. Bibbiani goes towards the expectation of success, because Bibbiani indicates that anti-Parkinson's drugs can be delivered via EVA implant.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 71, 75, and 78 and 59-61, 77, 81 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of US 5,604,198 to Poduslo et al. and US 5,618,553 to Kelleher.

Patel was discussed above.

What is lacking from Patel is:

1) the elected drug lisuride, and

2) a washed implant.

The teachings of Poluslo and Kelleher were discussed above.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use lisuride in place of the drug of Patel, and to wash the implant as taught by Kelleher. The motivation for using lisuride comes from Poduslo's teaching that lisuride is useful for treating Parkinson's disease. Thus, the artisan using the implant of Patel, but wishing to treat Parkinson's disease, would use lisuride instead of the drug of Patel. The artisan would expect success, because the EVA implant is non-erodable, and thus the artisan would only need to determine the appropriate dosing of lisuride (as compared to the dosing of Patel's drug), which is a matter of mere routine optimization. The motivation for washing comes from Kelleher's teaching that washing can remove an initial drug burst, if such is not desired.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 71, 75, and 78 and 59-61, 77, 81 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of US 5,604,198 to Poduslo et al., Bibbiani, and US 5,618,553 to Kelleher.

Patel was discussed above.

What is lacking from Patel is:

1) the elected drug lisuride, and

2) a washed implant.

The teachings of Poluslo, Bibbiani and Kelleher were discussed above.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use lisuride in place of the drug of Patel, and to wash the implant as taught by Kelleher. The motivation for using lisuride comes from Poduslo's teaching that lisuride is useful for treating Parkinson's disease. Thus, the artisan using the implant of Patel, but wishing to treat Parkinson's disease, would use lisuride instead of the drug of Patel. The artisan would expect success, because Bibbiani teaches that anti-Parkinson's drugs can be delivered from EVA implants. The motivation for washing comes from Kelleher's teaching that washing can remove an initial drug burst.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 71, 75, and 78 and 59-61, 77, 81 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of US 5,604,198 to Poduslo et al. and US 3,689,634 to Kliment.

Patel was discussed above.

What is lacking from Patel is:

1) the elected drug lisuride, and

2) a washed implant.

The teachings of Poluslo and Kliment were discussed above.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use lisuride in place of the drug of Patel, and to wash the implant as taught by Kliment. The motivation for using lisuride comes from Poduslo's teaching that lisuride is useful for treating Parkinson's disease.

Thus, the artisan using the implant of Patel, but wishing to treat Parkinson's disease, would use lisuride instead of the drug of Patel. The artisan would expect success, because the EVA implant is non-erodable, and thus the artisan would only need to determine the appropriate dosing of lisuride (as compared to the dosing of Patel's drug), which is a matter of mere routine optimization. The motivation for washing comes from Kliment'ss teaching that washing can remove impurities and polymerization initiators.

Claims 1, 2, 5, 7, 10, 15, 16, 17, 20, 22, 63, 65, 66, 72, 73, 76, 79, 82, 83, 84, 85, 86, and 4, 9, 19, 49, 50, 51, 52, 54, 55, 67, 68, 69, 71, 75, and 78 and 59-61, 77, 81 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view of US 5,604,198 to Poduslo et al., Bibbiani, and US 3,689,634 to Kliment.

Patel was discussed above.

What is lacking from Patel is:

1) the elected drug lisuride, and

2) a washed implant.

The teachings of Poluslo, Bibbiani and Kliment were discussed above.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use lisuride in place of the drug of Patel, and to wash the implant as taught by Kliment. The motivation for using lisuride comes from Poduslo's teaching that lisuride is useful for treating Parkinson's disease. Thus, the artisan using the implant of Patel, but wishing to treat Parkinson's disease, would use lisuride instead of the drug of Patel. The artisan would

expect success, because Bibbiani teaches that anti-Parkinson's drugs can be delivered from EVA implants. The motivation for washing comes from Kliment'ss teaching that washing can remove impurities and polymerization initiators.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 5/13/2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman
Art Unit 1618